

PCT

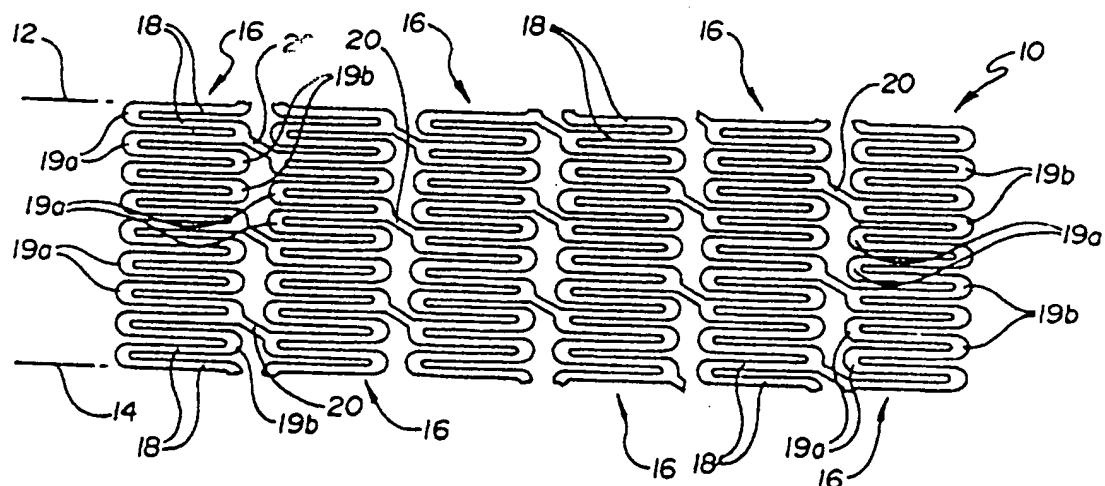
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: A61F 2/06 // A61B 17/12		A1	(11) International Publication Number: WO 96/26689
			(43) International Publication Date: 6 September 1996 (06.09.96)
(21) International Application Number: PCT/US96/02615			(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 28 February 1996 (28.02.96)			
(30) Priority Data: 08/396,569 1 March 1995 (01.03.95) US 08/511,076 3 August 1995 (03.08.95) US			Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US).			
(72) Inventors: BROWN, Brian, J.; 178 Jandle Avenue N.E., Hanover, MN 55341 (US). DAVIS, Michael, L.; 22020 Stratford Place, Shorewood, MN 55331 (US).			
(74) Agents: ARRETT, Oliver, F. et al.; Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402 (US).			

(54) Title: IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT



(57) Abstract

Segmented articulatable stent of open structure comprised of end-connected struts making up the segments with angular interconnects between segments.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LJ	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

This application is a Continuation of application Serial No. 08/396,569, filed March 1, 1995, the disclosure of which is hereby incorporated by reference.

Field of the Invention

This invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel. More specifically, it relates to a tubular expandable stent of improved longitudinal flexibility.

10

Background of the Invention

Stents are placed or implanted within a blood vessel for treating stenoses, strictures or aneurysms therein. They are implanted to reinforce collapsing, partially occluded, weakened, or dilated sections of a blood vessel. They have also been implanted in the urinary tract and in bile ducts.

Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding and some are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon.

20

An example of the latter type is shown in U.S. Patent No. 4,733,665 to Palmaz, which issued March 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

25

A type of self-expanding stent is described in U.S. Patent No. 4,503,569 to Dotter which issued March 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Other types of self-expanding stents not made of shape memory material are also known.

30

This invention is directed to stents of all these types when configured so as to be longitudinally flexible as described in detail hereinbelow. Flexibility is a desirable feature in a stent so as to conform to bends in a vessel. Such stents are known in the prior art. Examples are shown in U.S. Patent No. 4,856,516 to

Hillstead; U.S. Patent No. 5,104,404 to Wolff; U.S. Patent No. 4,994,071 to MacGregor; U.S. Patent No. 5,102,417 to Palmaz; U.S. Patent No. 5,195,984 to Schatz; U.S. Patent No. 5,135,536 to Hillstead; U.S. Patent 5,354,309 to Shepp-Pesch et al.; EPO Patent Application 0 540 290 A2 to Lau; EPO Patent Application 5 No. 0 364 787 B1 to Schatz, and PCT Application WO 94/17754 (also identified as German Patent Application 43 03 181).

Generally speaking, these kinds of stents are articulated and are usually formed of a plurality of aligned, expandable, relatively inflexible, circular segments which are interconnected by flexible elements to form a generally tubular body which is capable of a degree of articulation or bending. Unfortunately, a problem with such stents is that binding, overlapping or interference can occur between adjacent segments on the inside of a bend due to the segments moving toward each other and into contact or on the outside of a bend the segments can move away from each other, leaving large gaps. This can lead to improper vessel support, vessel trauma, flow disturbance, kinking, balloon burst during expansion, and difficult recross for devices to be installed through already implanted devices and to unsupported regions of vessel.

A diamond configuration with diagonal connections between each and every diamond of each segment is also known but such closed configurations lack 20 flexibility.

It is an object of this invention to provide a longitudinally flexible stent of open configuration that avoids these problems and exhibits improved flexibility (radially and longitudinally) in the stent body segments thereof rather than in flexible joints between the segments.

25

Summary of the Invention

To this end, the invention provides a tubular expandable stent, comprising: a plurality of cylindrical shaped open cylindrical segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment 30 being defined by a member formed in an undulating flexible pattern of interconnected substantially parallel struts with pairs thereof having alternating interconnecting end portions to define the periphery of the expandable stent segment, and in which the connected end portions of paired struts in each segment, before the

stent is expanded, are positioned substantially opposite to connected end portions of paired struts in adjacent segments. The segments are interconnected by a plurality of interconnecting elements extending from some of the connected end portions on one segment to some of the connected end portions on adjacent segments in such a 5 manner that there are three or more legs between points of connection from one side of each segment to its other side. Additionally, the connecting elements extend angularly from connecting end portion of one segment to connecting end portion of an adjacent segment, not to an opposite connecting end portion on an adjacent segment, whereby upon expansion of the stent the adjacent segments are displaced 10 relative to each other about the periphery of the stent body to accommodate flexing of the stent within paired struts without interference between adjacent segments, rather than by means of articulating flexible connectors between segments. As a result, the connectors between the segments are not intended to flex or bend under normal use.

15

Brief Description of the Figures

Figure 1 shows a flat view of an unexpanded stent configuration according to the invention.

20 Figure 2 shows the pattern of Figure 1 in a tubular, unexpanded stent. Figure 3 shows an expanded stent of the configuration shown in Figure 1.

Figure 4 shows a flat view of an alternate unexpanded stent configuration according to the invention.

25 Best Mode Description of the Invention

Turning to the Figures, Figure 1 and Figure 2 show a fragmentary flat view of an unexpanded stent configuration and the actual tubular stent (unexpanded), respectively. That is, the stent is shown for clarity in Figure 1 in the flat and may be made from a flat pattern 10 (Figure 1) which is formed into a tubular shape by 30 rolling the pattern so as to bring edges 12 and 14 together (Figure 1). The edges may then joined as by welding or the like to provide a configuration such as that shown in Figure 2.

The configuration can be seen in these Figures to be made up of a plurality of adjacent segments generally indicated at 16, each of which is formed in an undulating flexible pattern of substantially parallel struts 18. Pairs of struts are interconnected at alternating end portions 19a and 19b. As is seen in Figure 1, the 5 interconnecting end portions 19b of one segment are positioned opposite interconnecting end portions 19a of adjacent segments. The end portions as shown are generally elliptical but may be rounded or square or pointed or the like. Any configuration of end portions is acceptable so long as it provides an undulating pattern, as shown. When the flat form 10 is formed into an unexpanded tube as 10 shown in Figure 2, the segments are cylindrical but the end portions 19 of adjacent segments remain in an opposed position relative to each other.

A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configuration. It may also be chemically etched or EDM'd (electrical discharge machined) to form an appropriate 15 configuration.

Interconnecting elements 20 extend from one end portion 19 of one segment 16 to another end portion 19 of another adjacent segment 16 but not to an oppositely positioned end portion 19 of an adjacent segment 16. There are at least three struts included between the points on each side of a segment 16 at which an 20 interconnecting element 20 contacts an end portion 19. This results in the interconnecting elements 20 extending in an angular direction between segments around the periphery of the tubular stent. Interconnecting elements 20 are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one segment to another extending upward! 25 in one case and downwardly in another, although all connecting elements between any pair of segments are substantially parallel. Figure 1, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

As a result of this angular extension of the interconnecting elements 30 20 between adjacent segments and loops, upon expansion of the stent as seen in Figure 3, the closest adjacent end portions 19 between segments 16 are displaced from each other and are no longer opposite each other so as to minimize the possibility of binding or overlapping between segments, i.e., pinching.

The number of interconnecting elements 20 may vary depending on circumstances in any particular instance. Three per segment are satisfactory for the configuration shown and at least three will be used typically.

The alternate design shown in Figure 4 includes longer struts 18a in 5 the two end segments 16a than in the intermediate segments 16. This allows the end segments (16a) to have less compression resistance than the intermediate segments (16), providing a more gradual transition from the native vessel to the support structure of the stent. Otherwise, the configuration is the same as that shown in Figure 1.

10 As already indicated, this invention is applicable to self-expanding configurations, mechanically expandable configurations and to a wide variety of materials, including both metal and plastic and any other material capable of functioning as an expandable stent. For example, the stent may be of metal wire or ribbon such as tantalum, stainless steel or the like. It may be thin-walled. It may 15 be of shape memory alloy such as Nitinol or the like, etc.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar 20 with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A tubular, flexible, expandable stent, comprising:
a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating pattern of interconnected substantially parallel struts to define the periphery of the expandable stent body, and in which adjacent pairs of struts in a given segment are interconnected at opposite ends, interconnected ends of one segment being positioned substantially opposite to interconnected ends of an adjacent segment, and

10 a plurality of interconnecting elements each extending from an end of paired struts on one segment to an end of paired struts on an adjacent segment, the elements extending angularly from one end on one segment to another end, not to an opposite end, on an adjacent segment, the distribution of the elements being such that there are at least three struts between each connecting point on opposite sides of the segments,

15 whereby, upon expansion of the stent, the paired struts of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments
and without interference between adjacent segments.

20 2. The stent of claim 1 wherein the material of which it is comprised is metal.

25 3. The stent of claim 2 wherein the metal is a shape memory alloy.

4. The stent of claim 2 wherein the stent is a thin-walled tubular member.

5. The stent of claim 1 in a self-expanding configuration.

6. The stent of claim 1 in a mechanically expandable configuration.

7. The stent of claim 1 wherein the interconnecting elements between adjacent segments are of the same length.

30 8. The stent of claim 1 wherein the stent includes end segments and intermediate segments and the end segments of the stent include longer struts than the intermediate segments of the stent.

1 / 3

Fig. 1

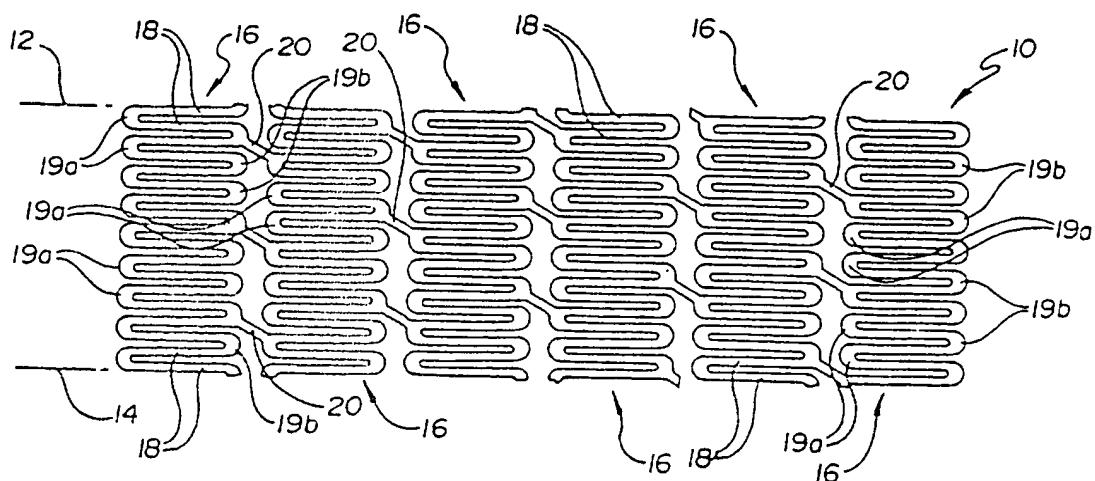
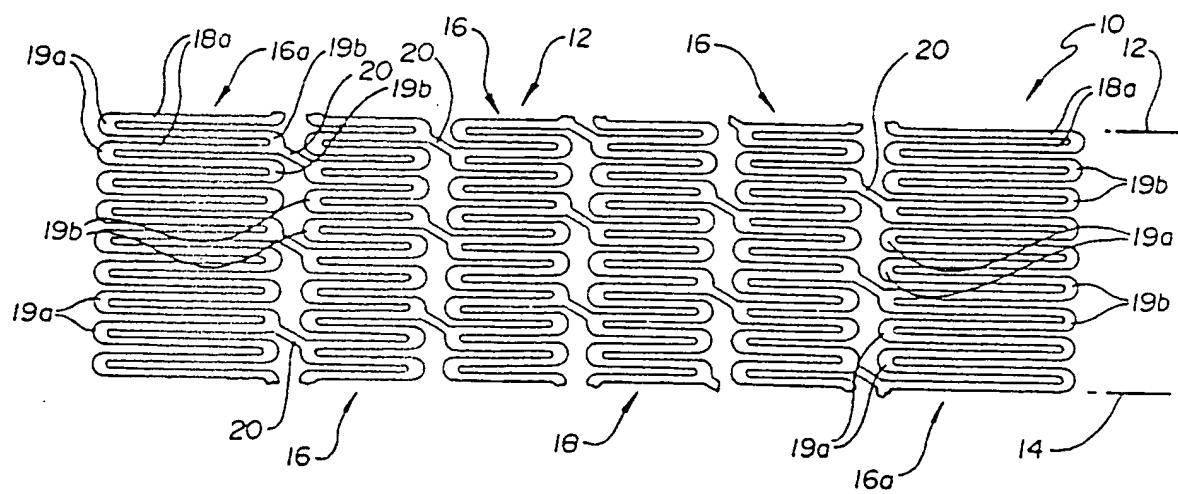
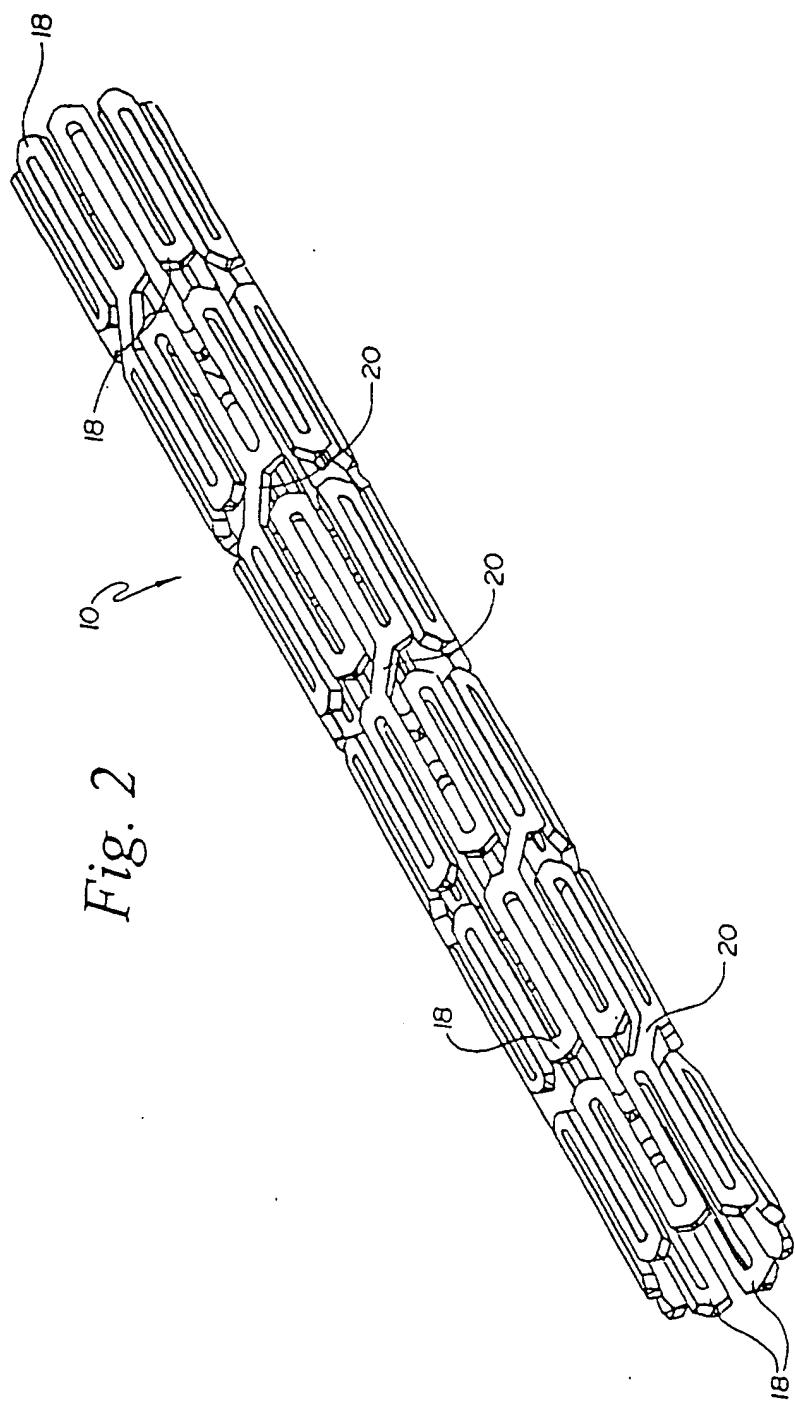


Fig. 4

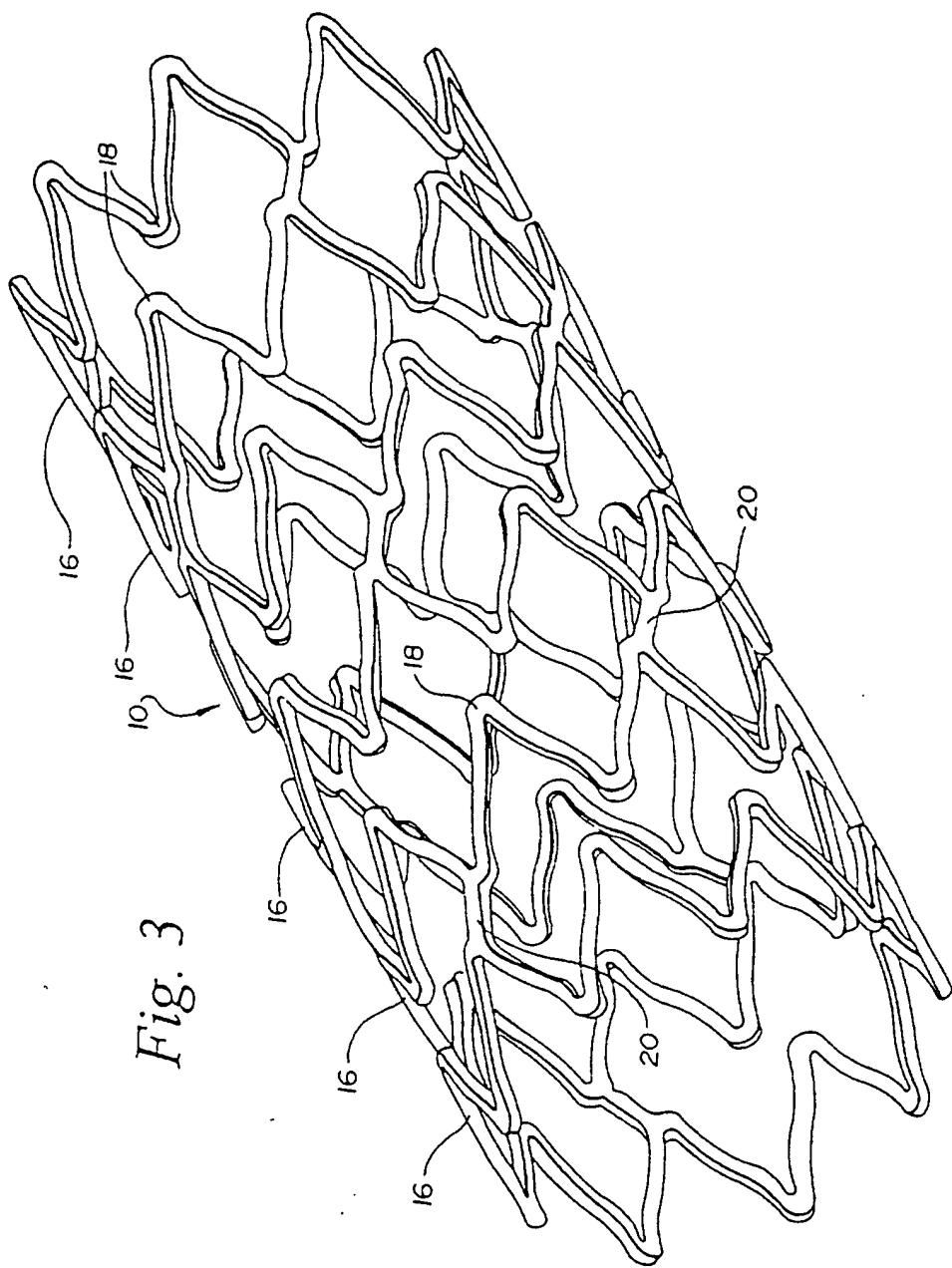


2 / 3

Fig. 2



3 / 3



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 96/02615

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/06 // A 61 B 17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

QUESTEL 2

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP, A2, 0540290 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.), 5 May 1993 (05.05.93), figures 4,5,11, abstract --	1-8
A	EP, A1, 0606165 (ETHICON INC.), 13 July 1994 (13.07.94), column 8, line 55 - column 9, line 20, figure 4 --	1-8
A	US, A, 5389106 (ALLEN J. TOWER), 14 February 1995 (14.02.95), figure 1, abstract -- -----	1-8

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

19 June 1996

22.07.96

Name and mailing address of the ISA/

European Patent Office, P.R. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 cpo nl.
Fax: (+ 31-70) 340-3016

Authorized officer

LEIF BRANDER

SA 128392

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/04/96

International application No.

PCT/US 96/02615

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A2- 0540290	05/05/93	CA-A-	2079417	29/04/93
		JP-A-	6181993	05/07/94
		US-A-	5421955	06/06/95
		US-A-	5514154	07/05/96
EP-A1- 0606165	13/07/94	NONE		
US-A- 5389106	14/02/95	WO-A-	9511720	^4/05/95

AMENDED CLAIMS

[received by the International Bureau on 5 September 1996 (05.09.96);
new claim 9 added; remaining claims unchanged (1 page)]

9. A tubular, flexible, expandable stent, comprising:
 - a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating pattern of interconnected substantially parallel struts to define the periphery of the expandable stent body, and in which adjacent pairs of struts in a given segment are interconnected at opposite ends, interconnected ends of one segment being positioned substantially opposite to interconnected ends of an adjacent segment, and
- 10 a plurality of interconnecting elements each extending from an end of paired struts on one segment to an end of paired struts on an adjacent segment, the elements extending angularly from one end on one segment to an end on an adjacent segment,
 - whereby, upon expansion of the stent, the paired struts of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

20

25

30

AMENDED SHEET (ARTICLE 19)